



DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Patent Term Extension

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments by any of the following methods:

- *Email:* InformationCollection@uspto.gov. Include “0651–0020 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to Raul.Tamayo@uspto.gov with “0651–0020 comment” in the subject line. Additional information about this collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:

I. Abstract

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or Department of Agriculture. Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is five years.

Under 35 U.S.C. 156(d), an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the application for patent term extension to provide a brief description of the activities undertaken by

the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

Under 35 U.S.C. 156(e), an interim extension may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect.

The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710-1.791. These rules provide for the public to, inter alia, submit 35 U.S.C. 156 patent term extension applications to the USPTO, request interim extensions and review of final eligibility decisions, and withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases extend the term of an original patent due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse determination of patentability. The patent term provisions of 35 U.S.C. 154(b), as amended by title IV, subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, require the USPTO to notify the applicant of the patent term adjustment in the notice of allowance and give the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination.

The USPTO may also reduce the amount of patent term adjustment granted if delays were caused by an applicant's failure to make a reasonable effort to respond within three months of the mailing date of a communication from the USPTO. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701-1.705.

The information in this collection is used by the USPTO to consider whether an applicant is eligible for a patent term extension or reconsideration of a patent term adjustment and, if so, to determine the length of the patent term extension or adjustment.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651-0020.

IC Instruments and Forms: There are no forms associated with this collection.

Type of Review: Revision of a Previously Existing Information Collection

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 1,340 responses per year. The USPTO estimates that approximately 25% of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity of the situation, to gather the necessary

information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 6,187 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: \$2,536,670.00. The USPTO expects that attorneys will complete these applications. The professional hourly rate for attorneys is \$410. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is \$2,536,670.00 per year.

#	Item	Estimated Time for Response (hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate (\$/hr) (d)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	25	95	2,375	\$410
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	1	10	10	\$410
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	25	4	100	\$410
4	Initial Application for Interim Extension Under 37 CFR 1.790	20	2	40	\$410
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	\$410
6	Response to Requirement to Elect	1	15	15	\$410
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	\$410
8	Declaration to Withdraw an Application to Extend Patent Term	2	1	2	\$410
9	Petition for Reconsideration of Patent Term Adjustment Determination	3	1,200	3,600	\$410
10	Petition for Reinstatement of Reduced Patent Term Adjustment	4	10	40	\$410
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2	1	2	\$410

#	Item	Estimated Time for Response (hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate (\$/hr) (d)
	Total	-----	1,340	6,187	-----

Estimated Total Annual (Non-hour) Respondent Cost Burden: \$351,505.08.

There are no capital startup, maintenance, or operating fees associated with this collection. There are, however, annual (non-hour) costs in the form of postage costs and fees.

Customers may incur postage costs when submitting some of the items covered by this collection to the USPTO by mail. The USPTO expects that approximately 93 percent of the responses in this collection will be submitted electronically. Of the remaining 7 percent, the vast majority--98 percent--will be submitted by mail, for a total of 92 mailed submissions. The average first class USPS postage cost for a mailed submission is 49 cents. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this collection will total \$45.08.

The fees associated with this collection are being returned from their previous location in collection 0651-0072, which has been discontinued. These fees are listed in the accompanying table below.

#	Item	Estimated Annual Responses (a)	Filing fee (\$) (b)	Total Non-hour Cost Burden (\$) (a) x (b) = (c)
1	Filing an application for patent term adjustment	1,200	\$200	\$240,000.00
2	Request for reinstatement of term reduced	10	\$400	\$4,000.00
3	Extension of term of patent	95	\$1,120	\$106,400.00

#	Item	Estimated Annual Responses (a)	Filing fee (\$) (b)	Total Non-hour Cost Burden (\$) (a) x (b) = (c)
4	Initial application for interim extension (see 37 CFR 1.790)	2	\$420	\$840.00
5	Subsequent application for interim extension (see 37 CFR 1.790)	1	\$220	\$220.00
Total	-----	-----		\$351,460.00

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of postage costs and fees is \$351,505.08 per year.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, e.g., the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 16th 2016.

Marcie Lovett,

Records Management Division Director, OCIO

United States Patent and Trademark Office.

[FR Doc. 2016-19864 Filed: 8/19/2016 8:45 am; Publication Date: 8/22/2016]